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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,374	11/16/2006	Robert C. Getts	POLYPROBE 3.3-028	4347

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EXAMINER	
HORLICK, KENNETH R	
ART UNIT	**PAPER NUMBER**
1637	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,374	GETTS ET AL.	
	Examiner	Art Unit	
	Kenneth R. Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,9-11 and 14-21* is/are allowed.

6)☒ Claim(s) *2-8,12,13 and 22-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/25/05;11/29/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-8, 12, 13, and 22-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 2-8, 12, 13, and 32-34 are confusing because the language "wherein a) comprises" in claim 2 lacks proper antecedent basis, as there is no "a)" in claim 1. Correction is required.

B) Claims 3-5 are confusing because "the mRNA molecule" lacks proper antecedent basis. Claim 2 refers to an "mRNA transcript". Correction is required.

C) Claims 22-30, and 35-39 are confusing because of the language "sRNA". Previous claims refer to "sense RNA"; clarification is required for consistency.

D) Claim 31 is confusing because of the language "with the detectably labeled cDNA of claims 27, 28, 29, or 30", as these claims are drawn to methods and not to labeled cDNA. Thus it cannot be determined what is encompassed. Clarification is required.

E) Claims 37-39 are confusing because it does not appear that claim 37 properly further limits claim 36. That is, since the enzymes recited in claim 37 are species of those required in claim 36, it would appear that "further comprising" in claim 37 is not appropriate. Perhaps "wherein the enzyme for attaching is terminal deoxynucleotidyl transferase and the enzyme for ligating is T4 DNA ligase" is intended. Clarification is required.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 31 is rejected under 35 U.S.C. 102(e) as being anticipated by Kiyama et al. (US 2002/0102589)(provisional filing date of 06/27/01).

This claim is drawn to a method comprising contacting a microarray with a detectably labeled cDNA. As noted above, it is unclear what is encompassed by "labeled cDNA of claim 27, 28, 29, or 30" as those claims are drawn to methods.

Kiyama et al. disclose a method comprising contacting a microarray with a detectably labeled cDNA (see page 5, paragraphs 0207-0208, and the Example on page 8). This method cannot be distinguished from the claimed method.

5. Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Berninger et al. (US 5,194,370).

This claim is drawn to a kit comprising: a double-stranded RNA polymerase promoter having a sense strand and antisense strand, wherein the sense strand of said promoter comprises a single-stranded 3' overhang

sequence. It is noted that "instructional materials" are not given patentable weight, as they relate to an "intended use" for the kit rather than to a kit component.

Berninger et al. disclose such a kit in column 6, lines 30-42; also see Fig. 1.

6. Claims 1, 9-11, and 14-21 are allowable. Claims 2-8, 12, 13, 22-30, 32-34, and 36-39 are free of the prior art, but are rejected for other reasons. No prior art has been found teaching or suggesting a method comprising: attaching an oligodeoxynucleotide tail to the 3' end of a single-stranded cDNA molecule, followed by annealing and ligation of a double-stranded RNA polymerase promoter (such as is taught by Berninger et al.), followed by initiation of RNA transcription to produce RNA molecules. Also, there is no teaching or suggestion of modifying the kit of Berninger et al. to include at least one enzyme for attaching an oligodeoxynucleotide tail onto the 3' end of a single-stranded cDNA molecule.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

02/28/08